Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria™ for locally unresectable rectal cancer.

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Radiation Oncology-Rectal/Anal Work Group. Locally unresectable rectal cancer. Reston (VA): American College of Radiology (ACR); 2002. 10 p. (ACR appropriateness criteria). [30 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Locally unresectable rectal cancer

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Oncology
Radiation Oncology
Radiology

INTENDED USERS

Health Plans
Hospitals

Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of treatment procedures for locally unresectable rectal cancer

TARGET POPULATION

Patients with locally unresectable rectal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

1. Surgery, such as tumor excision or abdominoperineal resection, PLUS radiation therapy before, during, or after the surgical procedure WITH OR WITHOUT 5-fluorouracil (5FU)-based chemotherapy
    - Boost dose given by external beam radiation therapy postoperatively, intraoperative electron beam radiation therapy, or interstitial implantation with either conventional low-activity sources or high-dose-rate sources
2. Radiation and chemotherapies WITHOUT surgery

MAJOR OUTCOMES CONSIDERED

- Local control
- Cure rate
- Symptom palliation

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria™

Clinical Condition: Locally Unresectable Rectal Cancer

Variant 1: 56-year-old male presents with recurrent rectal bleeding and pain with defecation. Past history: diagnosis of rectal cancer 2 years ago that was treated with low anterior resection followed by 6 months adjuvant chemotherapy. Endoscopy now shows anastomotic recurrence 6 cm above anal verge that is biopsy positive for adenocarcinoma. Lesion fixed to pelvic sidewall on physical exam and confirmed on computed tomography (CT) of abdomen and pelvis. Diagnostic studies fail to document other sites of disease. At present, tumor is unresectable.

Treatment	Appropriateness Rating	Comments
Radiation Therapy		
50.4 Gy/1.8 Gy to pelvis with 5FU-based chemotherapy	8	
50.4 Gy/1.8 Gy to pelvis	6	
59.4-64.8 Gy/1.8 Gy to pelvis with 5FU-based chemotherapy	6	
59.4-64.8 Gy/1.8 Gy to pelvis	6	
30 Gy/3.0 Gy to pelvis with 5FU-based chemotherapy	4	
30 Gy/3.0 Gy to pelvis	2	

Treatment	Appropriateness Rating	Comments
Surgery		
Preoperative RT +/– 5FU-based chemotherapy and reevaluate operability	8	
Surgery after preoperative RT (if resectable) with 5FU and intraoperative boost	8	
Try tumor excision and abdominoperineal resection (APR) before external beam RT	2	
Perform no surgery	2	
5FU-based Chemotherapy Duration		
4-6 months after therapy to primary	8	
12 months after therapy to primary	2	
Induction chemotherapy prior to RT	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Abbreviations: 5FU, 5-fluorouracil; RT, radiation therapy

Variant 2: 56-year-old male presents with recurrent rectal bleeding and pain with defecation. Past history: diagnosis of rectal cancer 2 years ago that was treated with low anterior resection followed by 6 months adjuvant chemotherapy. Endoscopy now shows anastomotic recurrence 6 cm above anal verge, which is biopsy-proven adenocarcinoma. Lesion fixed to pelvic sidewall on physical examination (PE) and confirmed on CT. Also biopsy-proven single liver metastasis on right lobe in peripheral location. At present, pelvic tumor is unresectable.

Treatment	Appropriateness Rating	Comments

Treatment	Appropriateness Rating	Comments
Radiation Therapy		
50.4 Gy/1.8 Gy to pelvis with 5FU-based chemotherapy	8	
50.4 Gy/1.8 Gy to pelvis	4	
30 Gy/3.0 Gy to pelvis	2	
30 Gy/3.0 Gy to pelvis with 5FU-based chemotherapy	2	
Surgery		
Preoperative RT +/– 5FU & reevaluate operability	8	
Surgery after preoperative RT (if resectable) with 5FU and intraoperative boost	8	
Try tumor excision and APR before external beam RT	2	
Perform no surgery	2	
Surgery to Liver		
After resection of primary site	6	
After 3-6 months post-surgical chemotherapy	6	
Before resection of primary site, after preoperative RT	4	
Before resection of primary site, before preoperative RT	2	
5FU-based Chemotherapy Duration		
4-6 months after	8	

Treatment	Appropriateness Rating	Comments
therapy to primary		
12 months after therapy to primary	2	
Induction chemotherapy prior to RT	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 3: 56-year-old male presents with recurrent rectal bleeding and pain with defecation. Past history: diagnosis of rectal cancer 2 years ago that was treated with low anterior resection followed by 6 months adjuvant chemotherapy. Endoscopy now shows biopsy-proven anastomotic recurrence 6 cm above anal verge. Lesion fixed to pelvic sidewall on physical examination and confirmed on CT. Three biopsy-proven unresectable liver metastases involving both left lobe and hilar region. At present, pelvic tumor is unresectable.

Treatment	Appropriateness Rating	Comments
Radiation Therapy		
30 Gy/3.0 Gy to pelvis with 5FU-based chemotherapy	6	
50.4 Gy/1.8 Gy to pelvis with 5FU-based chemotherapy	6	
59.4-64.8 Gy/1.8 Gy to pelvis with 5FU-based chemotherapy	6	
30 Gy/3.0 Gy to pelvis	4	
50.4 Gy/1.8 Gy to pelvis	4	
59.4-64.8 Gy/1.8 Gy to pelvis	4	
Surgery		
Preoperative RT +/–5FU and reevaluate operability	8	
Surgery after preoperative RT (if resectable) with 5FU and intraoperative boost	4	

Treatment	Appropriateness Rating	Comments
Perform no surgery	4	
Try tumor excision & APR before external beam RT	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Clinical Condition: Locally Unresectable Rectal Cancer

Variant 4: 56-year-old male with severe pain that radiates to perineal region. Past history: diagnosis of rectal cancer 2 years ago that was treated with abdominoperineal resection (APR), pelvic radiation therapy (RT) totaling 50.4 Gy plus 5-fluorouracil (5FU), followed by 6 months adjuvant chemotherapy. CT of abdomen and pelvis shows mass that invades bony pelvis at sciatic notch. Diagnostic studies fail to document other sites of disease.

Treatment	Appropriateness Rating	Comments
Radiation Therapy		
10-30 Gy/2.0 Gy to pelvis with 5FU-based chemotherapy	6	Provided the small bowel is excluded from this field.
10-30 Gy/2.0 Gy to pelvis	4	Provided the small bowel is excluded from this field.
10-30 Gy/2.0 Gy to pelvis with 5FU-based chemotherapy + intra-operative radiation therapy (IORT) boost to pelvic sidewall	4	Provided the small bowel is excluded from this field.
Permanent radioactive implant of symptomatic lesion	2	
Surgery		
Reevaluate operability after external beam RT +/– 5FU	8	
Surgery post external beam RT +/– 5FU +	6	

Treatment	Appropriateness Rating	Comments
IORT boost		
Attempt tumor removal + IORT	4	
Reevaluate operability after permanent implant	4	
Perform no surgery	4	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Abbreviations: 5FU, 5-fluorouracil; RT, radiation therapy

Variant 5: 78-year-old female with Karnofsky Performance Status (KPS) 70 with rectovaginal bleeding. Past history: breast cancer treated by mastectomy alone 10 years ago and valvular heart disease. Endoscopy now shows biopsy-proven adenocarcinoma 6 cm above anal verge that is fixed to lower uterine segment, and posterior wall of vagina, and pelvic sidewall confirmed by CT. Diagnostic studies fail to document other sites of disease.

Treatment	Appropriateness Rating	Comments
Radiation Therapy		
50.4 Gy/1.8 Gy to pelvis with 5FU-based chemotherapy	8	
30 Gy/3.0 Gy to pelvis with 5FU-based chemotherapy	4	
30 Gy/3.0 Gy to pelvis	2	
50.4 Gy/1.8 Gy to pelvis	2	
Surgery		
Preoperative RT +/– 5FU-based chemotherapy and reevaluate operability	8	

Treatment	Appropriateness Rating	Comments
Surgery after preoperative RT with 5FU and IORT boost	8	
APR before external beam RT	2	
Perform no surgery	2	
Chemotherapy		
4-6 months after therapy to primary	8	
12 months after therapy to primary	2	
Induction chemotherapy prior to RT	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 6: 38-year-old male with rectal bleeding. Endoscopy now shows rectal tumor, pathologically confirmed as adenocarcinoma, 4 cm above anal verge with extension to anus and adjacent perianal subcutaneous tissues. Past history is positive for familial polyposis. Patient is human immunodeficiency virus (HIV)-negative. Abdomen and pelvis CT shows internal iliac lymphadenopathy in addition to perirectal nodal involvement. Diagnostic studies fail to document other sites of disease.

Treatment	Appropriateness Rating	Comments
Radiation Therapy		
50.4 Gy/1.8 Gy to pelvis and perineum + 5FU-based chemotherapy	8	
50.4 Gy/1.8 Gy to pelvis and perineum	4	
30 Gy/3.0 Gy to pelvis and perineum	2	
30 Gy/3.0 Gy to pelvis	2	

Treatment	Appropriateness Rating	Comments
with 5FU-based chemotherapy		
Surgery		
Preoperative RT +/– 5FU-based chemotherapy and reevaluate operability	8	
Surgery after preoperative RT with 5FU and IORT boost	8	
APR before external beam RT	2	
Perform no surgery	2	
Chemotherapy		
4-6 months after therapy to primary	8	
12 months after therapy to primary	2	
Induction chemotherapy prior to RT	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 7: 38-year-old male with rectal bleeding. Endoscopy shows rectal tumor, pathologically confirmed as adenocarcinoma, 4 cm above anal verge with distal extension to anus and adjacent perianal subcutaneous tissues. Past history is positive for familial polyposis. Patient is HIV-negative. Abdomen and pelvis CT shows internal iliac lymphadenopathy in addition to perirectal nodal involvement. Diagnostic studies show multiple 0.5 cm asymptomatic lung metastases and single 2 cm liver metastasis in right lobe.

Treatment	Appropriateness Rating	Comments
Radiation Therapy		
50.4 Gy/1.8 Gy to	8	

Treatment	Appropriateness Rating	Comments
pelvis and perineum +5FU-based chemotherapy		
30 Gy/3.0 Gy to pelvis and perineum +5FU-based chemotherapy	6	
30 Gy/3.0 Gy to pelvis and perineum	2	
50.4 Gy/1.8 Gy to pelvis and perineum	2	
Surgery		
Preoperative RT +/– 5FU–based chemotherapy and reevaluate operability	8	
Surgery after preoperative RT with 5FU and IORT boost	6	
Perform no surgery	6	
APR before external beam RT	2	
Chemotherapy		
4-6 months after therapy to primary	8	
12 months after therapy to primary	2	
Induction chemotherapy prior to RT	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Abbreviations: 5FU, 5-fluorouracil; RT, radiation therapy; IORT, intra-operative radiation therapy; APR, abdominoperineal resection

Refer to the original guideline document for a summary of the literature review pertaining to locally unresectable rectal cancer.

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate selection of treatment procedures for patients with locally unresectable rectal cancer
- In patients with tumors that cannot be resected despite the use of high-dose radiation therapy, radiation therapy with 5-fluorouracil (5FU)–based chemotherapy can produce good palliation of symptoms (i.e., bleeding, pelvic pain, and sometimes obstructive symptoms), and in rare situations, tumor cure.

POTENTIAL HARMS

Toxicity of chemotherapy

Subgroups Most Likely to be Harmed:

Known human immunodeficiency virus (HIV) infection per se is not a contraindication to the use of standard recommended treatments. Patients with cytopenia, or with frank manifestations of acquired immunodeficiency syndrome (AIDS), however, may have a decreased ability to tolerate certain treatments, especially cytotoxic chemotherapy. A patient's overall performance status, complete blood count (CBC), and T cell counts (CD 3/4 status) should be considered in selecting appropriate therapy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other

imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Radiation Oncology-Rectal/Anal Work Group. Locally unresectable rectal cancer. Reston (VA): American College of Radiology (ACR); 2002. 10 p. (ACR appropriateness criteria). [30 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 (revised 2002)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria™.

GUIDELINE COMMITTEE

ACR Appropriateness Criteria™ Committee, Expert Panel on Radiation Oncology-Rectal/Anal Cancer Work Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Joel E. Tepper, MD; Bruce D. Minsky, MD; Nora A. Janjan, MD; Madhu J. John, MD; Seth A. Rosenthal, MD; David Ota, MD; Leonard Saltz, MD; Steven Leibel, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It updates a previously published version: Locally unresectable rectal cancer. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):1481-90.

The ACR Appropriateness Criteria™ are reviewed after five years, if not sooner, depending upon introduction of new and highly significant scientific evidence. The anticipated next review date for this topic is 2007.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Print copies: Available from American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 31, 2003. The information was verified by the guideline developer on April 21, 2003.

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